

CEPS SPECIAL REPORT

*Thinking ahead for Europe*

Transatlantic MRAs: Lessons for TTIP?

Jacques Pelkmans and Anabela Correia de Brito

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Abstract

It is striking that there is little or no mention in the TTIP debate so far of the US-EU Mutual Recognition Agreement (MRA) concluded in 1998. At the time, expectations of the gains from the MRA were high. One should expect the MRA to be instructive for TTIP and entail some lessons to be learned for today's attempt to lower technical barriers to trade (TBTs) across the North Atlantic. We offer an analysis of the 1998 MRA, the difficulties in the prior negotiations and those during the implementation phase, the subsequent and present status of sectoral approaches. The MRA experience revealed clearly how difficult it is to accomplish the acceptance of all relevant aspects of conformity assessment of the trading partner for the mere purpose of testing and certifying export goods on the requirements of the importing economy. The MRA has succeeded only in a few sectors. However, the ambition in TTIP with respect to TBTs is said to go so much further. It is therefore important for all those involved or interested in TTIP to learn the lessons of this early exercise in lowering TBT costs.

This paper reaches two main conclusions: i) the US-EU MRA was only partially successful and only for some one-fifth of the export flows at the time: a disappointing outcome and a far cry from the expectations of business and political leaders; and ii) the EU's attempt to 'balance' the negotiations in 1995 by bringing in three relatively competitive sectors did not work out – it was precisely there that problems accumulated. It is critical that domestic regulators must be satisfied during and after the negotiations that their pursuit of health, safety, environment and consumer protection objectives will not be watered down in any way.

Some lessons for TTIP

Lessons drawn include, among others:

- (a) MRAs are not about regulatory change (by definition), but if initial regulatory cleavages between trading partners are too wide, conditions become so restrictive that parties may regard them as a denial of the very purpose of the MRA.
- (b) There are incentives to opt for alternatives in the market for the formalised designation of conformity assessment bodies in the MRA and these are often cheaper and faster, while equally qualified.
- (c) Even in heavily regulated sectors such as medicines and medical devices, the narrow MRA has been superseded by near-global forms of effective cost-reducing cooperative (i.e. not treaty-based) regulatory alignment, a confirmation of the OECD approach that governments should think in terms of an entire spectrum of forms of regulatory cooperation.

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Transatlantic MRAs: Lessons for TTIP?

Jacques Pelkmans and Anabela Correia de Brito*

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1. Introduction and purpose

The ongoing negotiations between the European Union and the United States to create a Transatlantic Trade and Investment Partnership (TTIP) are largely about reducing regulatory barriers, especially technical barriers in goods markets. It is hoped to be accomplished by a broad range of instruments of regulatory cooperation, both within sectors and horizontally. This is often presented as breaking new ground and achieving appreciable economic gains in some sectors. It is also held to be an example for the world in that advanced regulatory cooperation to accomplish major reductions in TBTs (technical barriers to trade) will be agreed for the first time outside deep common markets. However, both of these assertions are incorrect. It seems to have been forgotten that, some 20 years ago, the US and the EU were negotiating a Mutual Recognition Agreement (MRA) in order to lower the costs of TBTs hindering transatlantic market access in six industrial sectors. It is striking that, in the TTIP debate so far, there is little or no mention of the US-EU Mutual Recognition Agreement (MRA) concluded in 1998.¹ At the time, expectations of the gains from the MRA were high in business and in trade policy circles. Both business in the TABD² and government negotiators (e.g. in the EU-US summits and at ministerial/Commissioner level) were committed to the process at the highest levels. MRAs are a tractable example of reducing TBT costs because they are based on a treaty, relatively modest in ambition and closely focused on sectors and technical competences. One should expect the **MRA to be instructive for TTIP** and entail some lessons to be learned for today's attempt to lower TBTs across the North Atlantic.

This CEPS Special Report will analyse the 1998 MRA, the difficulties in the prior negotiations and those during the implementation phase, the subsequent and present status of the six sectoral annexes and (briefly) the addition of a separate MRA on marine equipment. We draw a number of conclusions and policy lessons from this experience. It is good to realise that the MRA experience revealed clearly how difficult it is to accomplish the acceptance of all relevant aspects of conformity assessment of the trading partner for the mere purpose of testing and certifying export goods on the requirements of the importing economy. This modest purpose is all that a MRA is supposed to achieve: a MRA neither questions the domestic regulatory

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¹ There is also a US-EU Veterinary Equivalence Agreement (1998), which will not be discussed in this paper. The reader is referred to Tangermann & Josling (2014) for assessment and context.

² Trans-Atlantic Business Dialogue, led by CEOs from both sides.

regimes, or their objectives, nor the technical requirements or conformity procedures. There is no harmonisation whatsoever. Yet, this regulatory cooperation has succeeded only in a few sectors. The ambition in TTIP with respect to TBTs is said to go so much further. It is therefore important for all those involved or interested in TTIP to learn the **lessons of this early exercise** in lowering TBT costs.

2. Preparing MRA negotiations: drivers

The origins of the MRA go back to the second half of the 1980s when the EU began to deepen its internal market with new methods of removing regulatory barriers. The ambition and the speed of what was called “EC-1992”³ attracted the attention of the US business and policy communities, for fear of a ‘Fortress Europe’ but also expressing a keen interest to maintain or improve market access. Such attention was anything but surprising because trade and FDI (Foreign Direct Investment) interconnectedness over the North Atlantic had already become profound. During the late 1980s, the US began informal talks about a much closer involvement of the US when preparing EU decision-making on technical regulation and directly in European standardisation⁴. The menu of options for the US was limited. The US wanted to avoid a deterioration of relative market access, with the costs of TBTs dwindling inside the EU but not for US exporters. At the same time, harmonisation was not considered as an option. Indeed, for both the EU and the US it was basically a new kind of trade policy: regulatory trade policy. The crux was to come up with a new ambitious design for trade policy making between the two partners. For years, informal talks and tiny accomplishments⁵ yielded little.⁶ The partners had their own regulatory systems and what was a TBT from the perspective of an exporter, was regarded, by the importing partner, as a natural corollary of the duty to protect SHEC objectives⁷ via their regulation and organisation of conformity assessment. From 1986 onwards, the US and the EU began to publish annual surveys of market access barriers (to one another’s markets) with an emphasis on TBTs and SPS (Sanitary and Phyto-Sanitary measures about animal and plant health)⁸. There was a declared willingness to open up their economies

³ What EC-1992 exactly amounted to, how ‘deep’ it was, what type of proposals were enacted and how successful the seven-years internal market programme was, can be had from e.g. Pelkmans (2006, chapter 5) and Pelkmans (1994). A well-informed political economy account is in Egan (2001).

⁴ The famous statement from US Commerce Secretary Mosbacher in 1989 that the US wanted a ‘seat at the table’.

⁵ For example, in 1990 a MoU was agreed between the Commission (DG Enterprise) and the FDA on GMP in pharmaceuticals.

⁶ In 1990, US/EU talks of good intent led to the Transatlantic declaration, without firm proposals.

⁷ SHEC stands for safety, health, environment and consumer protection.

⁸ These annual reports are foreshadowing the issues in the later MRA negotiations. Thus, the 1987 US National Trade estimates report on foreign trade barriers (by USTR) expresses considerable concern about the 1987 Commission proposals to develop harmonised European standards for telecoms equipment (p. 100) and the 1990 Commission report on US trade barriers and unfair trade practices (p. 18) is quite alarming about the enormous fragmentation of electrical safety requirements for products and instalment (some 2700 entities at all levels are said to impose divergent requirements), with lost sales thought to be some 15 % of total sales. Telecoms equipment and electrical goods have been the economically most important sectors in the MRA negotiations.

but without much of a link with, let alone a structural involvement, of regulators or regulatory authorities. It is against this background that the emergence of the MRA has to be understood.

The first drivers of the eventual MRA date back to the late 1980s and early 1990s, which were hey-days for trade diplomacy, whether in Geneva for the Uruguay Round,⁹ or the emergence of APEC (on the initiative of Australia) and its intensification in 1993, the conclusion of NAFTA and the shaping of the EEA. The EU made it clear by the early 1990s that there was no such thing as Fortress Europe in the deeper internal market and that the Commission was mandated to negotiate MRAs.¹⁰ The US-EU MRA negotiations began in earnest in 1994¹¹. Since market access to the post-1992 EU was also of concern to other OECD countries, the EU offered to negotiate with e.g. Australia and New Zealand, Japan and Canada as well.

In 1995 the Madrid EU-US summit set up a New Transatlantic Marketplace (NTM). US business leaders initiated a transatlantic business summit with CEOs from European companies to help drive the process of negotiating the MRAs with the EU. Several (rough) estimates of cost reduction of the intended MRAs were floated (up to beyond \$1.5 billion) and time-to-market gains were emphasized by business as well. There is informal evidence¹² that some business sectors considered the MRAs as an opportunity to also obtain domestic regulatory reform in the US in sectors where conformity assessment was seen as unduly heavy, slow and costly (in particular, requirements from the FDA and OSHA). With the NTM focusing, inter alia, on the MRAs under negotiation, and given the political attention at the highest political level, European business leaders also became interested.¹³ The result was a unique initiative of a CEO-led Trans-Atlantic Business Dialogue (TABD)¹⁴ which often succeeded in formulating common views and positions on technical and sector-specific dossiers. The TABD exercised firm and consistent pressure to ensure that the motto ought to be 'one standard, one test, accepted everywhere', across the North Atlantic, and in fact worldwide. Business leaders began to lobby in a concerted fashion in Europe and the US. Some lobbying brought concrete results: in the US, for example, they managed to get Congress to insert a new clause on MRAs and their facilitation in a revision of pharmaceutical legislation in 1997.

The fact that Trans-Atlantic relations were deepening in the run-up to the 1998 US-EU summit in London, creating the Trans-Atlantic Economic Partnership,¹⁵ and that EU MRA negotiations with other OECD partners went smoothly, eventually led to the signalling of the MRAs in 1997 and the formal conclusion in 1998 during the London US-EU summit.

⁹ Remember that the TBT Agreement of GATT was refined, among other things, with respect to MRAs.

¹⁰ By a Council of ministers decision of 21 September 1992.

¹¹ For fascinating and very detailed accounts of the negotiations, see Devereaux, Lawrence & Watkins (2006) and Shaffer (2002).

¹² See e.g. Devereaux, Lawrence & Watkins (2006) and Shaffer (2002).

¹³ The detailed history of the TABD is found in Green Cowles (1996) and Stokes (1996). See also Quick (2008).

¹⁴ The first meeting of TABD was held in Sevilla, just before the 1995 Madrid summit.

¹⁵ See Pelkmans (1998) for detailed analysis and discussion of context.

3. MRA treaty and implementation

3.1 Treaty structure and scope

Table 1 gives a summary of the MRA. The 'Framework' (umbrella) specifies the 'conditions by which each party will accept or recognise results of CAPs ¹⁶, produced by the other party's CABs or authorities, in assessing conformity to the importing party's requirements' (art. 2). This is the purpose of the MRA. Art. 2 clarifies that the objective of such mutual recognition is to provide 'effective market access'. Apart from the pre-able, 11 main provisions are listed in the top panel of Table 1. Much of it is procedural, e.g. about what designation precisely is, designation procedures, recognition conditions, transition periods for 'confidence building', rules for suspension and withdrawals (of CABs), some administrative provisions and a general proviso on the preservation of US and EU regulatory authority.

This is followed by six sectoral annexes covering 1) Telecoms equipment; 2) Electro-Magnetic Compatibility (EMC); 3) Electrical safety for appliances (and indeed also for telecoms equipment); 4) medical devices; 5) Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) for pharmaceutical products; and 6) recreational craft (basically, boats for leisure).

Table 1. Structure of the EU-US MRA

<u>Framework</u>	
<ul style="list-style-type: none"> • Pre-ambule, emphasizing market access, encouraging harmonisation and equivalent assurance • Specifying definitions (e.g. 'designations') • Specifies conditions by which each party will accept or recognize results of CAPs • Transition periods (confidence building) • Designation and listing procedures • Suspension rules of CABs • Idem for withdrawals • Monitoring of CABs • Exchange of information and contact points • Joint committee (plus sectoral ones) • Preservation of regulatory authority • Suspension of recognition obligations 	
<u>Sectoral Annexes</u>	
Telecoms Equipment	Specification of laws and requirements; CAPs; listing of authorities; designation; subcontracting; transitional arrangement: 24 months.
Electro-Magnetic Compatibility (EMC)	Similar setup as for telecoms equipment.
Electrical Safety	Similar setup as for telecoms equipment; cross-linkages to telecom and EMC. In EU, complete lab assessments under US OSHA procedures (but EU can do on-site visits).

¹⁶ CAP = conformity assessment procedures ; CABs = conformity assessment bodies

Recreational Crafts	Specification of laws and requirements; scope and coverage; designating authorities; CAPs; transition of 18 months; link with EMC and electrical safety.
Good Manufacturing Practices (GMP) for pharmaceutical products	Pre and post approval inspections; 3 year transition period; equivalence determination at end of 3 years; nature of recognition of inspection reports; transmission of reports; suspension; joint sectoral committee; safeguard clause; appendix with applicable laws; criteria for equivalence in appendix.
Medical devices	Scope (different in EU and US); product coverage (quality evaluation systems; product evaluation; post-market vigilance reports); transition period: 3 years; other aspects similar to pharma GMP; alert systems.

Source: Agreement on mutual recognition between the EC and the USA, OJEC, L 31/3 – 31/80 of 4 February 1999.

3.2 Obligations, general and structural

Art. 3 of the treaty says that the US (EU) “shall accept or recognise results of specified procedures used in assessing conformity to [...] provisions of the US (EU), produced by the other party’s CABs and/or authorities”. Once the transition periods have been successfully completed, such CAPs for this purpose assure conformity ‘equivalent to the assurance offered by the receiving party’s own procedures’. Art. 4 lists all the detailed provisions which follow (see also Table 1), and adds that the MRA shall not be construed to entail mutual recognition of standards or technical regulations. There is also – besides transition periods, suspension of listed CABs, withdrawal of listed CABs, monitoring of CABs, suspension of recognition obligations – a termination clause.

The sectoral obligations are far more detailed, with specifications of laws and requirements, the enumeration of CAPs and authorities and transition periods. Clauses may sometimes have a meaning that is not easily understood from legal texts. Thus, the subcontracting provision in telecoms in fact reflected a tradition of US producers to let US CABs subcontract certification to Notified Bodies in the EU. In this way they built up durable trusted relationships. Moreover, the costs of duplicative testing (which the MRA was meant to reduce or eliminate) were already reduced via private alternatives. The same is true for leisure boats. Whereas EMC, electrical safety and recreational craft have no appendices and telecoms equipment a minor one, the pharma GMP one has five appendices (with the many criteria for equivalence in appendix 4) and the one on medical devices two appendices, but in addition a 21 pages table specifying hundreds of medical devices types under US legislation. The likely reason for this is that, in the EU, medical devices of lower risks classes are under the New Approach with SDoC,¹⁷ whereas in the US the FDA certifies them all; also, the risk classification of such devices differed somewhat between the US and the EU.

¹⁷ Self-certification (with the technical file available for authorities) leading to a Suppliers Declaration of Conformity.

The sectoral obligations and the details seem relatively ‘light’ in the cases of telecoms, EMC and recreational craft, heavier for electrical safety (with OSHA lab assessment procedures) and most heavy for pharma GMP and medical devices. The latter also has a post-vigilance process with reporting, presumably a kind of market surveillance.

3.3 Transition periods

The transition periods differ between the sectors due to complexity, the staff and resources needed and the differences in requirements between the US and the EU. There are indications from the literature that these differences also had to do with concessions to regulators who were not so willing. The shortest period foreseen is in recreational craft: 18 months. For telecoms, EMC and electrical safety the period is 24 months, but it ought to be noted that, in electrical safety, this also included lab assessment under OSHA specifications (however, in the EU, done by EU authorities). Electrical safety (for lower voltages) in the EU is under SDoC, and regulated by the low voltage Directive (and a host of European standards in its wake, very often aligned with global IEC standards) and, eventually, market surveillance. Therefore, lab assessments for Low Voltage products – and under specifications presumably different from world lab certification standards – do not exist in the EU, and in those days the EU had no system of European accreditation yet. For pharma GMP and medical devices, the transition period was three years. The success of the tests and experience during that period are a prerequisite for the MRA in these sectors to work.

4. From treaty to implementation

4.1 Implementation issues

Dependent on the sector, implementation of the sectoral MRAs has been relatively smooth, difficult or a stumbling block. Three sectors proved to be relatively easy - telecoms equipment, EMC and recreational craft – although only two Annexes (Telecoms and EMC) are in operation today. The first two had been central aspects of the MRA right from the beginning, and especially telecoms was rapidly turning into a truly global equipment market, based more and more on international standards. In telecoms by June 2001,¹⁸ the US had designated 23 CABs, and 43 for EMC. The EU had designated a similar number of CABs for EMC. In 1998 the EU relaxed its rather strict 1992 telecoms equipment directive towards one where SDoCs would be allowed. This self-certification provision meant that the designation of US CABs for telecoms equipment to be sold in the EU had become much less important. Recreational craft has a simple annex on safety aspects and a short transition period. The need for a MRA in this sector arose from the EU’s requirement of certification by a Notified Body; the US Coast Guard, the relevant US authority, already permitted to self-certify recreational craft. However, US exporters did not exercise much demand for US CABs able to obtain certification (on EU requirements); they preferred to continue using pre-existing subcontracting arrangements with EU CABs (probably, Notified Bodies) as they had built up long-run relations.¹⁹ The

¹⁸ See Shaffer, op. cit., p. 14

¹⁹ Shaffer, op. cit., p. 17 notes, only UL applied to be a US CAB under this annex but must have lost interest since the Commission Newsletter on MRAs of April 2012 states that no US CABs are designated. See trade.ec.europa.eu/doclib/docs/2012/may/tradoc_149385.pdf

recreational craft annex has not been in operation since 2006 – as a consequence of a revision of the EU directive in this area, adding emissions and noise requirements, and thereby moving beyond ‘safety’ issues, the focus in the annex, as well as in US legislation and in their conformity assessment.

Matters turned out to be a good deal more difficult in electrical safety. The EU saw the electrical safety annex as an imbalanced set-up because US exporters had relatively easy access – in terms of compliance costs and time-to-market – to the EU market given the Low Voltage directive (with SDoCs), whereas EU exporters faced regulatory reviews and approvals by OSHA. But OSHA was unsatisfied by the way the EU filled in the designation procedure: the EU accepted, without significant review, applications from the 15 EU Member States, largely in languages other than English.²⁰ Once the MRA had been agreed, OSHA insisted to conduct on-site reviews – which, for the EU, went against the spirit of the MRA – and began asking a fee in October 2000, given the cost burden of the process. In fact, there are signs that there was little actual co-operation at all in the joint sectoral committee. Perhaps, with a greater degree of willingness and co-operative spirit, the EU CABs could have been capable without any effort to submit applications in English! On the other hand, section VI of the electrical safety annex says clearly that “... CABs from the EC shall be designated by the EC authorities ...” and “OSHA shall rely on the EC designating authorities... for conducting on-site reviews at the respective Member States’ CABs”. The upshot was that OSHA rejected a number of applications on the basis of languages and incompleteness, typically issues that could have been addressed in a properly functioning sectoral committee. This refusal was threatening not only this specific sectoral MRA, and indirectly that of telecoms equipment (as electrical safety plays a role), but the entire MRA for reasons of ‘imbalance’ and a lack of trust. The designation of European CABs by OSHA was of course critical, given the regulatory regime for electrical goods in the US. But the acrimony ran much deeper because both the Commission and European industry felt strongly that the heavy approval system of OSHA was an unnecessarily burdensome and (by virtue of the low risks of these goods) unjustified barrier to market access. After all, the EU experience showed that using SDoCs worked well and this was usually cheaper whereas time-to-market was much less problematic. Strictly spoken, all this is no issue in a MRA, which by definition takes the two regulatory regimes as given, and solely focuses on avoiding duplicative conformity assessment. However, the WTO TBT Agreement rules that, if TBTs are unnecessarily burdensome and unjustified, they are forbidden and ought to be replaced by a justified and less burdensome regulatory regime. For EU industry, having – at the time – a structural trade surplus despite the market access barriers, even a successful resolution of the designation-of-CABs by OSHA would have been considered only as a minor success. Business opportunities would be much greater if self-certification of low-voltage electrical goods²¹ would be allowed by OSHA, just as it was in the EU for many years. Apart from a few quotes in Shaffer (op. cit.) and Devereaux et al. (op. cit.), suggesting that this deeper issue of distinct regulatory regimes for electrical goods was a bone of contention even when not formally part of the MRA, there is no evidence that attempts were undertaken to better appreciate each other’s regulatory regimes, as a first step to come to possible solutions, including the eventual recognition of SDoCs from companies operating in the EU under the Low Voltage directive and related (European, and indeed often world [IEC])

²⁰ Shaffer, op. cit. There were 11 EU official languages in the late 1990s.

²¹ Which, for OSHA, includes electronic equipment as well.

standards. All that emerges from the literature is the repeated remarks from OSHA officials about the Commission's failure to understand that this issue is one of occupational health and safety – that is, for US workers – and not 'the' market in general without distinction between workers and consumers, as was customary in the EU given low risks. However, many years later, when US-EU regulatory cooperation was deepened by establishing the Transatlantic Economic Council in 2007, the issue was addressed in detail, as summarised in section 5.

On medical devices, the story is little different, only more complicated. Regulatory culture, views on risks and sensitivities about the balance of costs and benefits of (how far) bringing risks down for patients all differed between the EU and the US. The FDA was stricter in its risk classification of some medical devices and it systematically practiced (centralised) pre-market approval via designated CABs as well as factory inspections, also abroad. Largely in contrast, the EU approach to medical devices was mainly based on the New Approach with self-certification, except for high-risk devices (such as pace makers) for which 3d party certification by Notified Bodies was required. But none of this required pre-market approval. The details of these inspections, data requirements and some technical aspects of clinical tests, etc. also differed between the US and the EU, indeed, as it turned out, even differed sometimes between EU Notified Bodies.

In pharmaceuticals the problems were probably even greater. Although the agreement is on GMP, the definitions of GMP of the US and the EU are *not even harmonised* in the annex: in Art. 1.3, *both* definitions have been included, with a clause stating that the parties have agreed to 'revisit' these concepts. The core of the annex is the recognition of the 'equivalence of the regulatory systems of the parties' (Art, 2, called – in the wording of this article itself – the 'cornerstone of this annex'). The three years transition 'aimed' to arrive at this recognition which seems more like an 'endeavour' than a fully-fledged MRA. The FDA felt that not only did it have to review multiple EU directives and related EU documents but also each Member State's implementing legislation, regulatory structures and practices. Before recognising an EU country's 'equivalence', the FDA required EU countries to engage their officials in joint training and joint inspections.²² All this suggests that the underlying idea of mutual recognition of assuming that other countries also care about the health and safety of their citizens and patients, as a starting point to set up a MRA, was firmly lacking. In addition, in both the cases of medical devices and pharmaceuticals, the agreed confidence building activities were not completed – and were not able to resolve key technical challenges to implementation of the annexes. At the same time, one has to recognise that the EU internal market for medicines was still seriously incomplete. Although the US does not enjoy a perfectly single market either, it does have a single, independent regulator. When the MRA was being negotiated, the EMA just initiated its work (1995). There was no way it could be regarded, at first, as a natural and experienced counterpart of the FDA, with sufficient competences. Moreover, although considerable harmonisation of medicines regulation had taken place, Member States' regulators still maintained major influence and significant residual powers with respect to marketing authorisations. For instance, in GMP – the subject of the US-EU MRA in pharma – common EU rules were only laid down in 2001 and further

²² Shaffer, op. cit., p. 20, quotes a FDA official that the FDA has 'refused to compromise its mission of protecting health for balance of trade purposes' whilst, at the same time, claiming that the FDA received insufficient resources for the additional and costly burden of implementing the MRA. In fairness, the FDA faced, to some extent, a similar problem across 50 US states and Puerto Rico.

guidelines in 2003. In addition, the pricing of medicines in the EU is regarded as a national competence, for social reasons (e.g. national re-imbursement systems sometimes leaving prices free, yet in other EU countries, prices are purposefully kept very low). However, the upshot of that two-tier governance was still a fragmented internal market at the time - we shall see that major improvements have been witnessed since those days. It is therefore not entirely unreasonable to argue that, perhaps, the EU was not ready internally to live up to the requirements of an effective MRA in medicines, in turn rendering the FDA even more hesitant. Of course, one can nevertheless maintain that the FDA was unusually difficult, because MRAs on pharmaceuticals with countries such as Canada, Japan and Switzerland were negotiated, too, and initial difficulties were eventually overcome to some degree.

4.2 The sectoral MRAs after five years

By 2003, three sectoral annexes were operational: telecoms equipment, operational since 14 December 2000; EMC, operational since 14 December 2000; and recreational craft, operational from 1 June 2000 to 2006. Since EMC is of importance for both electrical goods and telecoms equipment, this helped the telecoms sector to some extent, but it meant little for electrical goods.

Electrical safety had not gone into operation due to the tension between the Commission and OSHA. After OSHA's rejection of CABs designated by EU countries, the Commission felt that letter and spirit of the MRA were violated. In May 2002, assertions circulated in the press²³ that the EU was likely to suspend the electrical annex or withdraw from it. In June 2002 discussions were held on the pharma annex as well. The press²⁴ suggested that US experts felt the Commission was ambiguous about the annex because it feared that GMPs of individual EU countries would appear to be inconsistent. The two sides 'agreed to disagree'. Hence, the electrical annex was never made operational (and suspended²⁵ but not terminated) and the pharma one has never come into operation, but regulatory co-operation and information exchange exist (the annex has neither been suspended nor terminated). Medical devices had seen an extra transitional period of 2 years, but in 2003 the entire annex became defunct. Formally it is not in operation and no CABs are designated. Precisely in 2003 the Commission undertook its regular review of the three medical devices directives from the 1990s²⁶. In showing that a number of deficiencies had to be addressed, it may be seen as echoing some of the apparent concerns of the FDA: the Commission noted that both the designation and monitoring of the Notified Bodies left much to be desired, more clarity had to be ensured about clinical evaluation requirements, post-market surveillance had to be improved and issues around 'design review' had to be solved as well. This eventually led to a slight upgrading of these directives as proposed in 2005²⁷ and agreed shortly thereafter (as Dir. 2007/47). But of course the 2003 intentions for improvements fell far short of what would have been required for a process of regulatory convergence with the US. Thus, the MRA in medical devices remained a dead letter. The Commission's 2012 MRA newsletter states that regulatory co-

²³ As quoted by Shaffer.

²⁴ Idem

²⁵ On 21 Jan. 2003 ; see OJEC L 23 of 28 Jan 2003, p. 24

²⁶ See COM (2003) 386 of 2 July 2003 on medical devices

²⁷ See COM (2005) 681 of 2 July 2005

operation on medical devices between the two sides exists and the MRA annex is 'regarded as superseded' by this co-operation. The benefits of a MRA in medical devices are foregone but perhaps 'this' regulatory co-operation (after all, the FDA can and does designate/recognise foreign labs and GMP but on its own, not in a 'mutual' context) might nevertheless reduce the actual costs of accessing the US market for EU exporters. This will be briefly highlighted in section 5. For medicines, the MRA was dead already by 2001 but the EU gradually deepened its pharma regulation and procedures (also linked to EMA's work) while intensifying voluntary regulatory cooperation in the ICH (EU, US, Japan). Also, EMA did become a better recognised partner of the FDA, exemplified by a 2007 bilateral agreement on common market authorisation of orphan drugs, so as to ensure the large Transatlantic market in order to help recuperate the R & D expense.

4.3 Adding marine equipment

In April 2004 the MRA on marine equipment was formally agreed. It is a separate agreement. It is also different from 'traditional' MRAs in that there is far-reaching underlying harmonisation.²⁸ This harmonisation has not been negotiated between the US and EU but was already accomplished in a world forum, the International Maritime Organisation. Therefore, the MRA was relatively easy to conclude. Given alignment of both sides with IMO rules, designated products which comply with EU requirements (with certification by Notified Bodies) under the marine equipment directive will be accepted for sale in the US without any additional testing or certification, and vice versa for products conforming with US requirements (certified by the US Coast Guard). Whereas the US Coast Guard is in charge on the US side, the autonomous EU agency EMSA²⁹ is in charge in the EU. Some 49 types of marine equipment are covered.

5. Regulatory dynamics emanating from the MRA

5.1 The new EU MRA policy

The mismatch between many years of efforts and the actual outcome in 2003 led the EU to revise its MRA stance in 2004. This was not only due to the EU-US case. There were other disappointments with MRAs with other countries. For example, with Canada, medical devices turned out to be a problem due to a desire of Canada to have control over CABs in the EU; with Japan the pharma GMP annex is operational since 2004 but its coverage in terms of pharmaceutical products is partial, and the electrical one is formally operational but no CABs seem to have been designated. On the other hand, the five sectoral MRAs with Australia and New Zealand work well, although the amount of trade under them appears to be rather modest.

In a low-key document³⁰ the European Commission reviewed its MRA drive since the early 1990s and changed its priorities. The document first reviews the experience with MRAs. The

²⁸ What the Commission calls an 'enhanced' MRA, that is, with alignment of rules.

²⁹ European Maritime Safety Agency.

³⁰ A Commission Staff Working Paper, not a Commission 'communication'; see SEC(2004) 1072 of 25 August 2004, Priorities for bilateral/ regional trade related activities in the field of MRAs for industrial products and related technical dialogue

Commission notes that “[c]onfidence building becomes even more difficult where the technical requirements and overall regulatory approach of the two parties differ substantially”. “Our experience with the US and Canada MRAs has shown that, despite considerable investment on our side, good will is difficult to obtain in cases where there are substantial differences in the regulatory requirements / approach.” Where MRAs have been delayed or implementation was difficult, “... the market has found other ways of achieving the same result in a more efficient way”.³¹ The last point is of great importance: apparently, subcontracting (under retained responsibility of the CAB of the other party) is more efficient and quicker, not least because in this way well-established exporters can maintain a relationship with CABs on both sides, familiar with their products. The Commission explicitly considers two alternatives of MRAs: one is direct recognition of foreign CABs [but without, as in MRAs, conceding the *right* of such recognition to authorities of the other party], based on accreditation, in turn supported by international quality networks like ILAC and IAF ³²; another is about ‘voluntary schemes’ such as energy labels³³ promoting energy efficiency. The overall conclusion of the Commission paper is that i) ‘traditional’ MRAs without underlying ‘alignment’ are difficult to both negotiate and implement and that it is “not worth pursuing new negotiations on this type of MRA”; and ii) ‘enhanced’ MRAs, with such alignment or even harmonisation, offer the best prospects of implementation and trade facilitation. On bilateral MRAs, the Commission holds that “no more ‘traditional’ MRAs should be concluded with the US” and “no more sectors should be added” but efforts should concentrate on the three MRAs from 1998 which are operational.³⁴ For the MRAs with Australia and New Zealand, it is noted that they work well but trade impact is small and the expectation of some degree of regulatory convergence has not been borne out.

5.2 Do MRAs and regulatory reform interact?

In international regulatory co-operation, often the hope or expectation is expressed that, once authorities/regulators are confronted with regulatory solutions or systems employed in other countries, there will be, sooner or later, a ‘learning effect’. This learning could simply consist

³¹ All these quotes from p. 4.

³² ILAC (International Laboratory Accreditation Cooperation) has an arrangement with 85 signatories from 70 countries. It covers accredited testing and calibration laboratories since 2000 and accredited inspection bodies since 2012. Its laboratories and bodies conform with ISO/IEC 17011 (and related ILAC guidance documents), ISO/IEC 17025 and several other ISO 17000-series accreditation standards. There is a strict verification procedure and peer review. See www.ilac.org/ilacarrangement.html and Pelkmans & Correia de Brito (2015). IAF (the International Accreditation Forum) is specialised on accrediting (e.g. quality) management systems. The IAF Multilateral Recognition Agreement ensures recognition of equivalence of accreditation of other IAF member bodies to its own. IAF covers 63 countries with one body except for the US (with four) as well as six regional accreditation groups (including the EA, the European cooperation for Accreditation). See www.iaf.nu. See for further explanation on the actual or possible relation of these accreditation networks with MRAs in a worldwide context, see Pelkmans & Correia de Brito (2015).

³³ The Commission notes it had concluded a MRA with the EPA in the US on ‘Energy Star’ labelling.

³⁴ Added is a telling comment: “Other ‘enhanced’ type MRAs should be pursued only where... Agencies responsible for implementation are interested (our experience ... has been that political agreements cannot guarantee their implementation... when implementation is an independent agency’s responsibility)”.

of ‘familiarisation’, hence, lead to a more relaxed attitude when recognizing practices or institutions in other countries (like CABs) or, in a stronger form, the adoption of similar approaches via domestic regulatory reform. MRAs are based on the legal and political premise that domestic regulation, its objectives and institutions remain unaffected. MRAs deal strictly and only with conformity assessment in export country A on the product requirements as well as CAPs of importing country B, and vice versa - neither objectives, nor technical requirements nor CAPs are at issue. Indeed, the US-EU MRA is clear about this; moreover, art. 15 of the agreement confirms the ‘preservation of regulatory authority’ of the parties - its formulation is strict and refers to a wide scope. But such a starting point need not imply that nothing will actually change over time.

One can discern two types of regulatory reform linked to MRAs, and derived from the US-EU case: regulatory reform caused by the sectoral MRAs; and domestic reforms, independent from MRAs, but affecting the working of MRAs or even rendering them superfluous as alternatives (may) take over. As to the first category, Shaffer (op. cit., pp. 41-42) holds that the US-EU MRAs prompted some regulatory reform but that it was primarily the US which felt compelled to do so. The principal reason would be that inside the EU there was much experience of such processes of comparing national regulatory regimes whereas the US was unaccustomed to exposure, let alone to requests to adapt its practices. Three such changes are mentioned by Shaffer: (a) the US has adopted some international standards that mirror EU ones, (b) on two occasions US Agencies have begun to allow private CABs to test and certify (the FCC began to allow this for telecoms equipment in 1998; the FDA began, also in 1998, a programme for private testing and certification for most medical devices), inspired by the EU approach and insisted on by US business;³⁵ (c) coordination and oversight of private laboratories under a new NIST ³⁶ programme (in 1999), hoping for greater confidence with regulatory officials. One may also argue that the spread of MRAs to other OECD countries at the time would help the EU New Approach flexibilities to become more acceptable elsewhere, which, in turn, would increase the (business and public) pressure on the US to accept further regulatory reform.³⁷ Attractive as it might sound, the suggestion seems to be a little too easy because, as noted, Canada and Japan were most prudent on e.g. medical devices and electrical safety, and only Australia and New Zealand (already used to mutual recognition under the Trans-Tasman Mutual Recognition Arrangement) embraced the EU model in five sectoral MRAs, without however going for regulatory convergence. Alternatively, such a gradual reform process might emerge but with much greater time lags given the unquestioned priority of domestic regulators to serve the relevant SHEC objectives at all times.

The second type of regulatory reform consists of more or less autonomous domestic reforms which subsequently turn out to affect the MRAs and/or their operation. Of course, during the last two decades the issue of regulatory burdens and red tape has been prominent in all OECD countries, if not worldwide. In some cases, reforms reducing red tape or other ‘unnecessary’ burdens were directly relevant for the operation of the MRA for business. Linked to the MRAs (ex post) are EU reforms such as the revision of the telecoms equipment directive in 1998, allowing SDoCs, as well as the EU reform for EMC in 2004 (amending the 1989 directive) also

³⁵ Although US firms can now rely on private testing bodies, many still use *free* FDA inspections instead.

³⁶ The US National Institute for Standards and Technology, a body affiliated with the US Dept of Commerce.

³⁷ One advocate of this idea is Kalypso Nicolaidis (2000).

no longer requiring third party certification and hence relying on SDoCs. With SDoCs, one way of the two-way MRA is no longer needed. However, this also happened the other way around: in recreational craft, it is the EU which requires third party certification and the US accepts SDoCs. In Canada, for example, third party certification for EMC was abolished in 2003 and because that happened the year after in the EU as well, the MRA in EMC has become pointless. Whether deeper or wider regulatory reform on the basis of imitation of the regulatory regime of the partner has taken place is doubtful³⁸, except perhaps for medical devices. MRAs may well be the famous tail which cannot easily be expected to move the much bigger dog of domestic regulation.

In medical devices, however, after having initiated a prudent regulatory reform process in 2003 (see above), the EU undertook a more fundamental review of the regulatory regime for medical devices from 2008 onwards. The proposals in 2012³⁹ responded to a raft of weaknesses and the debates even became somewhat acrimonious once the PIP (breast implants) scandal broke out and repeated problems with artificial hips occurred. Proposals included amendments and clarification of the legislation, strengthen the designation and supervision of the Notified Bodies⁴⁰, strengthening the position of Notified Bodies vis a vis manufacturers (e.g. unannounced inspections), clarifying the obligations of producers and importers, expanding a European database, increase the traceability throughout the value-chain [using a Unique Device Identifier (UDI), a tool also discussed worldwide] and e.g. greater coordination between national authorities. In the subsequent debate, the EP rapporteur Ms. Roth-Behrendt and a large group of MEPs (as well as BEUC) advocated to move even closer to the US model by establishing a centralised EU pre-market approval model with a separate Agency for medical devices. A compromise solution of a special committee linked to EMA seemed to be agreeable in the spring of 2014, but the EU legislator has still not enacted the legislation. The point however is that what was thought – by EU negotiators – to be an overly tough US regime in the mid-1990s, was actually approximated to a considerable degree by the EU in recent years. Moreover, the slow-moving process of regulatory convergence in the Global Harmonisation Task Force has become more relevant with the new International Medical Device Regulators Forum, focused on global standards (such as ISO 13485), its pursuit of a worldwide UDI and e.g. a harmonised format for product registration submission. Altogether, the initial road of the MRA would now be less difficult but at the same time, this MRA approach seems to have been overtaken by a global consensus of leading countries to find global solutions. In this process, TTIP might well solidify the new global cooperation.

As far as medicines are concerned, one observes a gradual but steady improvement of the various regulatory aspects of the EU internal market since the early 1990s, also after the MRA in pharmaceuticals had failed in 2001. We already noted that common EU rules for GMP were enacted in 2001, with further guidelines in 2003. Nowadays, the EU has arrived at a system retaining the Member States competences (e.g. on re-imbursements and to some extent on medicines' safety) but fully coordinated with EMA oversight. Some experts hold that, today,

³⁸ See also Quick (2008) for a broader discussion of regulatory cooperation between the US and the EU and its inability of generating regulatory reform until 2008 inclusive.

³⁹ See COM (2012) 540 of 26 September 2012, Safe, effective and innovative medical devices and in-vitro diagnostic medical devices (etc.)

⁴⁰ Going somewhat beyond what is obligatory in Reg. 765/2008 for all New Approach products, including European accreditation

the EU has a more robust and quality- assured evaluation and drug approval system than the US. For instance, centralised applications for marketing approval are assessed by both a rapporteur and a co-rapporteur and draft assessments are shared with the whole network of national authorities. Also, various forms of regulatory cooperation have been developed outside the MRA, helped greatly by the fact that both the US and the EU have experienced medicinal Agencies by now. The FDA and EMA and/or the Commission and/or the Member States have cooperated in e.g. 'active pharmaceutical ingredients manufacturing' (such as harmonise the inspections, etc.), in change requests, paediatric medicines and pharmacovigilance (alert systems and common formats).

Getting around the MRA via regulatory alignment?

The notion that a MRA will only work well once regulatory systems have or develop a significant degree of convergence, is very different from the initial understanding of MRAs. The original idea behind a MRA is purely one of avoiding duplicative testing/certification, taking the regulatory regimes, including conformity assessment and inspections, of both parties as given. Indeed, a MRA is intrinsically a modest arrangement. However, the history of the US-EU MRA shows that there is some interaction between the MRA and domestic regulation or CAPs, as noted. But there is also evidence that MRAs make both regulators and other stakeholders realise even more that the core of the TBTs better be addressed as well, even if carefully and gradually, and preferably in cooperative (i.e. not treaty-driven) ways. In other words, regulatory alignment achieved by cooperative mechanisms might sometimes work better than a MRA treaty. We provide two striking examples of such attempts: a successful attempt in medicines ⁴¹ and a failure (so far) in electrical goods.

In medicines, the vexed problem of inspections of factories - seemingly hopeless in the first years of the MRA - has eventually been solved cooperatively by agreeing to have comparable rules and standards of inspection via PIC/S. Today, all Member States' agencies (but three) have joined PIC/S, a total of 28 agencies in 25 EU countries. The US became a member of PIC/S in 2011 after the compulsory assessment and the FDA has been actively participating ever since in all PIC/S meetings as well as in training and other activities. All PIC/S members now apply the audit check introduced by Canada. Experts and pharma companies underline that the observations and findings of EU and US inspectors are the same nowadays. Furthermore, the ICH global cooperation between the US, EU and Japan had become operationally more important precisely when the MRA was about to fail. Nowadays there are some 50 ICH Guidance documents (common approaches for determining efficacy, quality and safety of medicines, the most prominent one being ICH doc. Q 7) and this voluntary setting appears effective in reducing regulatory diversity. One specific accomplishment in saving (unnecessary) costs is the CTD (Common Technical Document): with this CTD, only one single file for the approval process is required with all the required data, and it is accepted in the US, the EU and Japan. One might regard this as a partial substitute of the MRA.

In electrical goods, the EU frustration about the failure of the MRA to lower market access costs did not go away. When the Transatlantic Economic Council was set up by US and EU

⁴¹ One can argue perhaps that the recent development in medical devices, in the International Medical Devices Regulators Forum (based on a global standard, a worldwide UDI and a harmonised format of product registration submission) promise to become effective routes towards regulatory convergence as well.

political leaders in 2007, a commitment was made to address this issue via regulatory cooperation. In 2008 the Commission submitted a proposal to OSHA to accept SDoCs for electrical goods falling under the Low Voltage directive. In 2010, a rather elaborate analysis was published by OSHA ⁴² of the Commission proposal to accept SDoCs, instead of 3rd party certification solely by NRTLs⁴³, for low-risk electrical goods. This lengthy document is interesting as it sheds light on what it takes to achieve effective regulatory cooperation with such agencies. What is positive in the approach is the maturity and analytical nature of the exchange between OSHA and the Commission, as well as other EU stakeholders, in sharp contrast with the acrimony of the late 1990s. Reducing the TBT that the Commission perceives – i.e. heavy and restricted 3rd party certification instead of SDoCs – for market access of electrical goods to the US market cannot be ‘negotiated away’: it can only be the result of an analysis of whether domestic regulatory obligations in the law (here the US OSH Act) are not negatively affected or undermined by allowing SDoCs of companies exporting from Europe. OSHA rejected the request from the EU. It based its decision (after two years of seeking a profound understanding of how the EU system works and what its health and safety records are) on two complementary assessments: one statistical (is there “a direct correlation between the method of protection and low rates of illness or injury”?) and one qualitative (assessing “the operation, attributes and elements of the [EU] system to determine whether it is likely to provide a high level of protection”).

This Special Report cannot do full justice to the reasoning and analysis of the OSHA Notice. But a few points can be made. First, in two ways the OSHA approach is more ambitious than is customary in the EU with respect to the Low Voltage directive: (a) OSHA insists on ‘hard’ statistical proof and found that the statistical data submitted falls short (in several ways) of providing substantive empirical evidence in favour of SDoCs; (b) OSHA must guarantee a ‘high level of worker protection’ (similar to what the EU treaty objective is) but it recalls US case law holding that OSHA is allowed to “deviate only modestly from the stringency required by section 6 (b) (5) for health standards” ⁴⁴, and then adds (on its own account) “which must eliminate significant risk [as in the EU, the authors] or reduce that risk to the maximum extent feasible”. It is the last part of the sentence that would seem to disregard a cost-benefit approach or a sense of proportionality. It is well-known in the economics of regulation that the marginal costs of avoiding risks to the maximum extent possible can be very steep indeed, with only minimum extra benefits obtained. Of course, this is a societal choice given the ‘right to regulate’ of every country. However, it is good to understand that it is plainly impossible to impose such rules for too many goods and services as it would become unpayable. There is always a risk remaining anyway and cost-benefit perspectives help one to realise whether it is worthwhile to engage in risk reduction ‘to the maximum extent feasible’ or better spend these additional resources for other purposes. Since Low Voltage electrical goods tend to be low-risk goods, the question is therefore whether much, if anything, is gained by imposing very costly regulatory regimes including conformity assessment by NRTLs or UL instead of SDoCs. Hence, what for OSHA is prudent risk regulation coupled to strict conformity assessment plus

⁴² Notice: Nationally Recognised Testing Laboratories: Suppliers Declaration of Conformity, OSHA, Washington DC, December 17, 2010 ; Federal Register Number 2010-31695 (ID : OSHA-2008-0032-0099).

⁴³ OSHA 3rd party certification must be conducted by Nationally Recognised Testing Laboratories, legally spoken, but in actual practice or due to nearly 30 US States’ laws, by UL.

⁴⁴ In the US, here, standards mean ‘regulatory requirements’

regular inspections, amounts (for the EU) to a TBT ‘unnecessarily’ hindering market access for EU exporters. Add to this the fact that, on the whole, EU electrical goods are competitive, with a structural trade surplus with the US for decades even with the higher access costs, and the contours of a profound disagreement in bilateral regulatory trade policy are sketched.

The OSHA Notice goes deep into the statistical evidence offered by EU stakeholders in order to substantiate the good EU record in electrical safety of these goods and the Agency finds the empirical evidence wanting on a number of plausible grounds. It also recalls samples of two subsectors in the EU where compliance had turned out to be bad, and used it against the EU (absent other reliable statistical information for all subsectors). Although compliance failures often consisted of (inappropriate) paperwork, not technical failures, a non-trivial share also showed technical failures. Relevant injuries and accidents statistics were compared and no clear evidence in favour of the EU system was detected. This led Europeans to complain that these statistics are either weak or incapable of identifying *why* such accidents happen: is it equipment failures or conduct or for other reasons?

The point here is that the light EU regime (because electrical goods are seen as low risk) does not invite heavy and systematic investment on accident statistics and across-the-board statistics from market surveillance ; indeed, there is no culture of permanent (re)justification based on evidence that regulation for such low risk goods works well. This means that the EU is at a disadvantage vis-à-vis a (US) regulator with huge resources and the power to impose 3rd party conformity assessment (also yielding better statistics). Subsequently, OSHA assesses the SDoC as a ‘reactive’ system. Although the Agency has the tendency to reason in favour of the eventual rejection, the weaknesses of the SDoCs, the problems in EU markets arising from a lack of annual inspections and the limitations of EU Member States’ market surveillance are nevertheless revealed systematically.

A number of partial alternatives to the OSHA-NRTL system are discussed and eventually rejected. Finally ⁴⁵, OSHA becomes a little defensive when it points out that, even when it were to grant SDoCs as a proof of compliance, it would need to massively invest in market surveillance (it suggests no less than \$ 360 million annually) ⁴⁶ and acquire additional powers e.g. for recalls. The Notice shows very well what it takes to overcome the more stubborn (perceived or actual) TBTs in TTIP. This does not mean that alignment or regulatory convergence is impossible but, rather, that one has to invest in the case for equivalence based on hard arguments and empirical evidence and one might, perhaps on both sides, have to be prepared to introduce selected reforms to render alignment acceptable for risk regulators. This is not impossible for electrical goods. A few years after the OSHA rejection, a review of the functioning of its NRTL’s system has been initiated due to a major dissatisfaction. This might still lead, perhaps in modest degrees, to partial regulatory alignment.

⁴⁵ It also rebuts the notion that the OSHA system is a TBT whereas it holds that the EU is less ‘free’ in market access than it asserts.

⁴⁶ Here one ought to realise that the OSHA regime is only covering electrical goods for professional use ; the massive consumer market in the US is not covered at all (unlike in the EU). The huge sum for market surveillance only for professionally used electrical goods therefore looks suspiciously like a convenient excuse.

6. Lessons or implications for TTIP

We draw two straightforward conclusions from this MRA experience and offer four lessons for TTIP.

The first conclusion is that the MRA of 1998 had failed for one half and was (is) successful for the other half; however, in trade flow terms, the MRA coverage was around 20 % of the 1995 total for five sectors (without the recreational craft one), with the EU experiencing a negative trade balance.⁴⁷ On the whole, a disappointing outcome and a far cry from the expectations of business and top decision makers in 1998. Second, the EU's attempt to 'balance' the MRA package in the negotiations – so typical for trade negotiators – did not work out. The concern of EU trade negotiators emerged from the narrowing down of 12 sectors, when the MRA talks began in earnest in 1994, to telecoms equipment and EMC only one year later. Sectors such as electrical goods, medical devices and medicines showed EU trade surpluses for many years and their inclusion in the MRA package would restore 'balance'. The US showed little enthusiasm for this balancing approach but eventually gave in. But precisely in the sectors brought in by the EU in 1995, problems – in particular by what the EU saw as a lack of flexibility on the part of the relevant independent US regulators – eventually led to a failure due to regulatory diversity in implementation. It confirms that 'regulatory trade policy' cannot be successfully conducted like classic trade diplomacy: domestic regulators must be satisfied during and after the negotiations that their pursuit of SHEC objectives will not be watered down in any way. Regulators should therefore (also) be in charge of regulatory trade policy, in TTIP and in other such negotiations.

From the experience of the 1998 US-EU MRA and related regulatory debates, we draw four lessons for mutual recognition of conformity assessment or, more ambitiously, attempts of regulatory convergence in TTIP.

- i. *MRAs are not about regulatory change, but if regulatory cleavages are too wide, MRAs can only work under such restrictive conditions, that partners may regard them as a denial of its very purpose.*

MRAs reflect a conscious choice of governments not to engage in regulatory change, and solely focus on reducing transaction costs of market access in case of regulated products. Both (or more) countries do this not unilaterally but jointly. Lowering transaction costs usually consists of reducing or eliminating duplicative controls/certification and tests, and this, in turn, can be achieved when both governments accept (subject to a safeguard clause only) that the government of the exporting country has set up a system which is competent in assuring conformity with the importing country's requirements. If this acceptance is lacking and country A insists on direct control for product x or own inspections of factories, the MRA risks degenerating into a heavy structure for processes that can also be executed *without* a MRA, namely unilaterally. In the run-up to TTIP, it was often heard that the failures of the US-EU MRA in three sectors was probably due to the difficulty in implementing the MRA across jurisdictions and agencies that may act (too ?) independently given their mandates and not in the spirit of the MRA. This may well have been true (and we quote informal evidence supporting this), but closer scrutiny shows that this is not the whole truth. As noted above, at

⁴⁷ In Devereaux et. al, op. cit., p. 314, 1995 trade flows are provided. On the EU side telecoms equipment exports to the US amounted to around 12 % of the total flows for the 5 sectors; on the US side, its telecoms exports amount to 23 % of total flows.

least in medicines and medical devices, the EU regimes at the time left something to be desired. With hindsight, the improvement of EU regulation as well as the tightening of conformity assessment and/or pre-market approval and GMP constitute important signals that the US regulators had justified substantive concerns as well. But it is equally important to recognise that much has changed in two decades. For example, GMP inspections no longer differ between the US and EU. Nowadays, more robust internal market regimes and some regulatory rapprochement should make it much easier to pursue effective regulatory cooperation (including or not, a MRA). One implication of this awareness is that a (new) MRA or such rules incorporated in TTIP would free resources for authorities to focus more inspection attention on higher-risk countries like India and China.

ii. MRAs are about (recognised) 3rd party certification and inspections, but there are incentives to opt for alternatives in the market, some of which have meanwhile developed international credibility.

MRAs are feasible in markets which are less heavily regulated, but ironically, in these cases they are also less needed because alternatives to MRAs (in particular, SDoCs) might serve as a lower cost and swift solution. When SDoCs are not permitted, other alternatives may nevertheless be used by market players. Thus, in particular large US (EU) exporters with a steady customer base (or as part of a value chain) in the EU (US) have a great interest in durable relationships with CABs. The costs of getting to know their products and the associated risks are lower and communication faster and easier when CABs regularly test their product range or new variants. It might also facilitate the planning of testing which may shorten time-to-market. In other words, for large and regular exporters there are costs of switching CABs and therefore they will favour subcontracting via 'their' CAB. Since the designated CABs typically have subsidiaries in many countries, and surely in the US and the EU, the actual working of the MRA is different from what was originally envisaged. The conventional operation of the MRA will then be significant only for new entrants or occasional exporters or in cases of overload. New entrants may well be SMEs, so for them and possibly the emergence of 'new' competitive rivalry, the MRA would still fulfil a useful function. One can extend this point further: if the MRA would be renegotiated, there would be a strong case for involving or recognising the international quality networks of CABs and accreditation bodies, thereby greatly facilitating the arrangements for business.

iii. MRAs in heavily regulated markets can only be expected to function properly once an advanced degree of regulatory alignment has taken place.

Medicines and high-risk medical devices are heavily regulated and that seems justified. Between the US and the EU, however, high-risk medical devices were excluded in the MRA. For low-risk medical devices, the FDA was simply unwilling to alter its approach (and control) – whilst the EU and its member states were probably not 'ready' given the then state of EU regulation and conformity assessment by Notified Bodies – whereas for pharmaceutical products 'only' GMP was at issue, be it both with pre- and post-approvals, but even that was at first an 'acceptance' bridge too far.⁴⁸ At the same time, cautious attempts were initiated at the global level to achieve greater regulatory cooperation for pharma and medical devices. Meanwhile, they have grown into cooperative efforts of regulatory alignment and effectively

⁴⁸ Shaffer reports a conspicuous difference between the US and Canada in this respect. Canada was capable of evaluating the 15 regulatory systems of EU countries within the transition period, and this period was shorter than in the US case. Note 221, p. 40.

so. Interestingly, this cooperation is amongst regulators, not trade negotiators. The experience suggests not so much that MRAs are impossible (e.g. pharma works with Canada for a few years now, and for the EU-Israel MRA since 2013), but that MRAs in such sectors are not suitable unless all stakeholders (including regulators) agree beforehand what it will take and that sufficient time is foreseen to evaluate and – above all – build trust. Confidence-building measures must be given time. But once regulatory alignment is initiated at a global level, this is much to be preferred. TTIP could of course attempt to reinforce such global cooperative efforts. It confirms an insightful inference from the OECD (2013) that governments should think in terms of a spectrum of forms of regulatory cooperation of which an MRA is one among many options. And although many such cooperative efforts are legally ‘soft’, some of them may nonetheless be effective in reducing the costs of TBTs.

iv. Once one attempts to propose modest ‘reforms’ of conformity assessment methods of US independent regulators, so as to reduce the costs of TBTs, and thereby get around the MRA, one should be prepared for a fully-fledged impact assessment, with the hard empirical evidence that it requires.

In the EU, and to some extent in circles of US business too, it is widely held that the implementation of the MRAs in sectors under the responsibility of independent US agencies was carried out in an overly rigid manner, without acknowledging the idea and spirit of mutual recognition. This tended to minimise the benefits of the MRA or caused failure. The costs of their CAPs and other requirements were regarded as unnecessarily high, certainly in comparison with the more widespread practice of relying on SDoCs in Europe. Curiously, there is no reference in the (scarce) literature about the early stages of the MRA to cost-benefit analysis, qualitative or quantitative. This is peculiar because US independent federal agencies routinely conduct cost-benefit analysis of their proposals, indeed, are often under the duty to do so. One reason for not doing so in the context of a MRA might have been that regulatory regimes of both parties are taken as given and are not to be questioned. The EU proposal in 2008 to persuade OSHA to accept SDoCs constitutes an attempt to get around the MRA and go for a mutual acceptance approach (here, of SDoCs) via a modest degree of regulatory alignment (in one sector). What happened was that OSHA undertook, given its remit and duties to provide extensive empirical evidence for such a change, a kind of impact assessment, with an emphasis on extensive consultation and statistical evidence about accidents and injuries, compared to those in the US. The EU, with ‘light’ regulation in electrical goods, was not fully prepared for that. The two-year process of exchange of arguments, regulatory approaches and empirical evidence, culminating in the reasoned rejection by OSHA of the EU request, reveals quite well what it takes to accomplish alignment of CAPs of an independent US regulator: ‘passing’ a kind of impact assessment, with hard empirical evidence, and a preparedness on both sides to initiate modest reforms in conformity assessment, as a result of a – preferably joint – analysis. This inference directly relates to the chapter on horizontal regulatory cooperation in TTIP.

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